

APPENDIX C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Celia C Chang
Art Unit : 1625
Applicants : Marianne Langston, Hooshang Shahriari Zavareh
Serial No. : 09/928,139
Filed : October 8, 2001
For : The Manufacture of Single Isomer Methylphenidate

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF DR. HOOSHANG S. ZAVAREH UNDER 37 CFR 1.132

Sir:

I, Hooshang S. Zavareh, Ph.D., c/o Amedis Pharmaceuticals Ltd., 162 Cambridge Science Park, Milton Road, Cambridge CB4 0GP, United Kingdom (formerly of Celltech R&D Ltd., Granta Park, Great Abington, Cambridge CB1 6GS, United Kingdom), hereby declare:

THAT, I am a co-inventor of the subject matter claimed in this Application;

THAT, I have read and understood the specification and claims of this Application;

AND, being thus duly qualified, do further declare:

Methylphenidate has two chiral centres in the same molecule. It is relatively easy to racemise the molecule at one such centre. In order to racemise one of the enantiomers so that all four are obtained, racemisation must occur at both centres. This involves abstraction of a proton. It is therefore surprising that an acid causes this racemisation to occur.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issuing thereon.

Further declarant sayeth naught.

Signed:

HS Zavareh
Dr. Hooshang S. Zavareh

Date:

15 July 2003